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EXAMINER

HAMILTON, MONPLAISIR G

ART UNIT PAPER NUMBER

2172

DATE MAILED: 07/09/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Am

Office Action Summary

Application No.

09/836,653

Applicant(s)

DURKALSKI, WESLEY PAUL

Examiner

Monplaisir G Hamilton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/13/01 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. Claims 1-20 are pending.

Priority

2. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Drawings

3. The drawings are objected to because of informalities noted on PTO-948, Notice of Draftsperson's Patent Drawing Review. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5963967 issued to Umen et al, further in view of Microsoft Press Computer Dictionary Third Edition.

Referring to Claims 1 and 20:

Umen discloses a method for creating a customized database (document) management system, the method comprising: providing a user with at least one question related to an anticipated use of the customized database (document) management system (Fig 3; col 6, lines 10-25);

receiving at least one answer to the at least one question from the user (col 6, lines 10-25);

retrieving a set of rules associated with the anticipated use of the customized database management system (col 6, line 50-col 7, line 15);

analyzing the at least one answer and the set of rules (col 2, lines 25-68; col 10, lines 45-55); and generating the customized database (document) management system according to the analyzing of the at least one answer and the set of rules (col 10, lines 45-55).

Umen does not disclose the claimed "customized database".

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Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more than a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 2:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the customized database management system is a clinical trials database management system (col 4, lines 55-65).

Referring to Claim 3:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the anticipated use is administration of a clinical trial (col 4, lines 1-20).

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Referring to Claim 4:

Umen discloses the limitation as discussed in Claim 3 above. Umen further discloses the set of rules is derived from clinical trials regulations (col 2, lines 1-68; col 6, lines 60-65; col 10, lines 45-60).

Referring to Claim 5:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the set of rules governs the at least one answer (col 9, line 60-col 10, line 30).

Referring to Claim 6:

Umen discloses the limitation as discussed in Claim 5 above. Umen further discloses generating creates a customized database that is in conformance with the set of rules and the at least one answer (col 10, lines 45-68).

Referring to Claim 7:

Umen discloses the limitation as discussed in Claim 1 above. Umen further discloses the providing a user with at least one question, the receiving at least one answer, the retrieving a set of rules, the analyzing, and the generating are all performed on a common Web site (col 4, lines 20-55).

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Referring to Claim 8:

Umen discloses a creation system for generating a customized database management system, the creation system comprising:

a computer configured to execute a first routine for asking a user at least one question related to a desired application for the customized database management system and for receiving at least one answer to the at least one question from the user (Fig 3; col 6, lines 10-25);

the computer further configured to execute a second routine for retrieving a set of rules associated with the desired application for the customized database management system (col 6, line 50-col 7, line 15);

the computer further configured to execute a third routine for processing an analysis of the at least one answer and the set of rules (col 2, lines 25-68; col 10, lines 45-55); and

the computer further configured to execute a fourth routine for generating the customized relational database management system according to the analysis (col 10, lines 45-55);).

Umen does not disclose the claimed "customized database".

Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more than a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized

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database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 9:

Umen discloses the limitation as discussed in Claim 8 above. Umen further discloses the customized database management system is a clinical trials database management system (col 4, lines 55-65).

Referring to Claim 10:

Umen discloses the limitation as discussed in Claim 8 above. Umen further discloses the desired application is a clinical trial (col 4, lines 55-65).

Referring to Claim 11:

Umen discloses the limitation as discussed in Claim 10 above. Umen further discloses the set of rules is in conformance with clinical trials regulations (col 2, lines 25-68; col 10, lines 45-55).

Referring to Claim 12:

Umen discloses the limitation as discussed in Claim 10 above. Umen further discloses a generated customized database management system is in conformance with the set of rules and the at least one answer (col 2, lines 25-68; col 10, lines 45-55; col 9, line 60-col 10, line 30).

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Referring to Claim 13:

Umen discloses the limitation as discussed in Claim 9 above. Umen further discloses the asking and receiving are handled by a dialogue box described by software executed by the computer (col 5, lines 10-20).

Referring to Claim 14:

Umen discloses the limitation as discussed in Claim 9 above. Umen further discloses the first routine, second routine, third routine, and fourth routine reside at a common Web site (col 4, lines 20-55).

Referring to Claim 15:

Umen discloses a method for creating a clinical trials database management system, the method comprising:

providing information descriptive of a particular clinical trial (Fig 3; col 6, lines 10-25);

providing a first set of rules in accordance with clinical trials governing regulations (col 2, lines 25-68; col 10, lines 45-55);

generating a second set of rules that conforms to the information and to the first set of rules (col 9, line 60-col 10, line 15); and

generating the clinical trials database management system to be compliant with the second set of rules (col 10, lines 45-60).

Umen does not disclose the claimed "customized database".

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Microsoft's Computer dictionary defines a document to be any self-contained piece of work created with an application program and, if saved on disk, given a unique filename by which it can be retrieved. Documents are generally thought of as word-processed materials only. To a computer, however, data is nothing more than a collection of characters, so a spreadsheet or a graphic is as much a document as is a letter or report. Therefore a document and the claimed customized database are equivalent.

At the time the invention was made, it would have been obvious to a person of ordinary skill in the art to modify the teachings of Umen to generate the claimed customized database/document. One of ordinary skill in the art would have been motivated to do this because it would provide a database that is in compliance with FDA clinical trials regulatory rules (col 2, lines 55-65).

Referring to Claim 16:

Umen discloses the limitation as discussed in Claim 15 above. Umen further discloses the clinical trials database management system is contained within a Web site (col 4, lines 20-55).

Referring to Claim 17:

Umen discloses the limitation as discussed in Claim 16 above. Umen further discloses the clinical trials database management system is operable on the Web site (col 4, lines 20-55).

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Referring to Claim 18:

Umen discloses the limitation as discussed in Claim 15 above. Umen further discloses the information descriptive of a particular clinical trial includes a user name, and data collection specifications (col 6, lines 10-20).

Referring to Claim 19:

Umen discloses the limitation as discussed in Claim 18 above. Umen further discloses the information descriptive of a particular clinical trial further includes specifications for data cleaning (col 10, lines 45-60).

Prior Art

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6513047 issued to Talley, Stephen C. Talley discloses a method and computer program product for managing and manipulating user-defined and system databases in a computing system. A database interface, which can be a graphical user interface, accesses a database configuration file containing descriptions of the contents of each of the databases. The database interface interprets the contents of each database in accordance with the configuration file, and provides for user access and manipulation of the contents of the databases.

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Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monplaisir G Hamilton whose telephone number is 1703-305-5116. The examiner can normally be reached on Monday - Friday (8:00 am - 4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kim Y Vu can be reached on 1703-305-4393. The fax phone numbers for the organization where this application or proceeding is assigned are 1703-746-7239 for regular communications and 1703-746-7238 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 1703-305-3900.

Monplaisir Hamilton
June 30, 2003

Shahid Al Alam
SHAHID AL ALAM
PATENT EXAMINER